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## The Endovascular Management of Thoracic Aortic Disease – Some Controversial Issues

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The use of stent-grafts to manage thoracic aortic disease is now a reality but many issues need to be addressed. This editorial presents the thoughts of the authors with a view to stimulating debate amongst the readers.

### Aneurysms

The published 30-day mortality following surgical repair of aneurysmal disease of the descending thoracic aorta is in the region of 2–21% with the majority of units reporting 5–15%.<sup>1–4</sup> However a recent audit of cardiothoracic units in Great Britain and Ireland showed a 34% mortality rate for procedures performed on bypass and 25% when performed without bypass.<sup>5</sup> Other complications of thoracic surgery include paraplegia or paraparesis in up to 5%, particularly where surgery extends beyond the 8th intercostal space, renal failure in 5%, stroke in 3%, cardiac and pulmonary problems in 10% and 28% of patients.<sup>4,6</sup> Postoperative recovery is often protracted with time spent on an intensive care unit, and long-term rehabilitation may be considerable. Understandably the potential benefits of a “minimally invasive” treatment utilising stent-graft technology are attractive. Most data arises from the U.S.A. The reported mortality rate is 0–9% with a paraplegia and stroke rate of less than 3%, and an incidence of renal insufficiency around 4% using commercially available devices.<sup>7</sup> The hospital stay has been reduced to an average of 3 days. Using first generation

“in-house” devices Dake demonstrated a 1 and 2 year survival of 81 and 73% that probably equates to the long-term results from surgery although good data to substantiate this long-term comparison is missing.<sup>8</sup> Other data are generally low volume. Grabenwoger treated 21 patients with a 100% technical success rate and two deaths (9.5%).<sup>9</sup> Won and colleagues managed 23 patients with aneurysmal disease.<sup>10</sup> All 11 patients with degenerative aneurysms were treated successfully whereas there were two failures from 12 patients with chronic dissections. There were no deaths or paraplegia within 30 days and 91% survival at 1 year. A series from Japan details 15 patients with chronic dissections who were successfully treated without death or paraplegia. No death or rupture occurred out to an average follow-up of 24 months.<sup>11</sup> Whilst these data support the use of stent-grafts there are a number of problems. Firstly the volume of data remains small with a lack of information on long-term outcomes. Secondly, the relative costs of the two therapies is unknown. Thirdly, we are all aware of the structural failure of abdominal stent-grafts. The data for thoracic work is smaller volume with shorter follow-up. However one major provider of thoracic stent-grafts has already voluntarily removed their device from the market because of stent and spine fractures. In order for patients to appreciate the short-term gain from the stent-graft compared to surgery, the devices must be robust enough to show longevity. Finally, in order to provide Grade A recommendations the current guidelines require at least one randomised controlled trial.<sup>12</sup> Herein lies the crux of the problem. Given the marked disparity in 30 day outcomes between surgery and treatment with stent-grafts it is difficult to conceive how clinicians can retain equipoise that would enable them to randomise patients between the two therapies. Without a randomised trial health

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Footnote. Many of the issues presented here arise from a stimulating meeting held recently at Guys Hospital, London.

policy makers may be reluctant to sanction the use of stent-grafts. This problem has recently been overcome in the U.K. with the insight and understanding of the Safety and Efficacy Register of New Interventional Procedures of the Medical Royal Colleges (SERNIP). Whilst this group has recommended that thoracic stent-grafts should only be placed as part of primary research (category C) they have recently agreed that submission of data to a National Thoracic Stent-Graft Registry fulfils this criteria. Hopefully other regulatory authorities will follow suite.

### Trauma

Traumatic thoracic aortic transections are an attractive situation in which to consider stent grafts. Only 14–18% of patients with this type of injury reach hospital alive and approximately 15–39% will die during or following surgery. Approximately 2.3–28% of patients will develop paraplegia, the higher rate being associated with the “clamp and sew” technique rather than the use of bypass or Gott Shunt.<sup>13</sup> Excellent results from endovascular repair have been reported, with 0–17% mortality and no paraplegia in four small series.<sup>14–17</sup> Whilst these data are small, and the long-term integrity of stent-grafts in patients, some of whom will be young, is unknown, the potential for a minimally invasive treatment to treat these extremely sick patients seems clear. More widespread application of this technique will require the instant availability of stent-grafts and the dissemination of this expertise to all major trauma centres.

### Acute Dissection

The majority of acute type B dissections are now managed medically with surgery being reserved for complications (rupture, refractory hypertension, localised false aneurysms, continued pain or branch vessel ischaemia) which results in a 30 day operative mortality of 31–64%.<sup>18–21</sup> If an abdominal operation is required then there is an 80% operative mortality.<sup>18</sup> Stent-grafts have been used primarily to manage acute branch vessel ischaemia complicating type B dissection. The largest series from Stanford demonstrated relief of ischaemia in 76% of cases; all cases of dynamic obstruction and 40% of cases where the obstruction is thought to be a combination of dynamic and static obstruction.<sup>22</sup> The early 30-day mortality rate was only 16%. Of importance was the observation that complete

thrombosis of the false lumen was achieved in 74% of cases, partial thrombosis in the rest and an associated reduction in the size of aorta and false lumen over time with no late deaths due to aortic rupture. Czermak has also treated six of seven patients (seven acute, two chronic) successfully.<sup>23</sup> The perception of the difference in outcomes between surgery and stent-graft therapy for complicated type B dissection has led to a number of approaches. Some clinicians now feel that stent-grafts should be considered the treatment of choice. This largely ignores the small volume of available data and lack of long-term outcome measures. Perhaps for them submission of data to a large registry should be mandatory. Others see the need for a randomised controlled trial (RCT). Unfortunately no funded study is currently available.

Even more controversial is the use of stent-grafts to manage uncomplicated acute type B dissections. The number of patients not offered surgery or stent-graft who die late or require subsequent intervention for late dissection related events that may be remedied by stent-graft induced thrombosis of the false lumen (i.e. late rupture, aneurysm formation, progression of ischaemia or dissection) is difficult to estimate from the literature but is probably approximately 12–30%.<sup>20,24,25</sup> It has been demonstrated that false lumen patency following dissection predicts both long term aneurysm formation and death,<sup>26</sup> and that stent-grafts induce false lumen thrombosis.<sup>22</sup> If the supposition that false lumen thrombosis stops late events is correct then stent-grafts may be able to stop delayed rupture of the aorta following type B dissection. However with no active intervention the false lumen will spontaneously thrombose in 50% of patients 5 years following type B dissection, and there are of course cost implications to a therapy that may only benefit 12–30% of patients in the long-term.<sup>26</sup> Currently health purchasers are unlikely to agree to the treatment of uncomplicated type B and a RCT is required.

### Terminology

The assessment of the value of value of stent-grafts in chronic dissections is confused by nomenclature. To many surgeons the clinical picture of chronic dissection is a patient who presents with a thoracic aortic aneurysm where imaging demonstrates a dissection that occurred many years ago. However chronicity is often used to describe a dissection of more than 2 weeks old and, using this definition, two recent publication has advocated stent grafts for chronic dissection.<sup>11,27</sup> Clearly there is a huge difference in the potential for

a thin floppy membrane of only 2 weeks old to move after stent-graft placement and allow relief of branch vessel ischaemia and closure of the false lumen when compared to a thickened septum present for many years. An improved classification is required before we can even start to assess the value of stent-grafts in this situation.

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